UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15 (d)
of The Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): **August 16, 2022**

OCUGEN, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-36751**	**04-3522315**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

11 Great Valley Parkway
Malvern, Pennsylvania 19355
(484) 328-4701
(Address, including zip code, and telephone number, including area code, of principal executive office)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8–K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a–12 under the Exchange Act (17 CFR 240.14a–12)

☐ Pre–commencement communications pursuant to Rule 14d–2(b) under the Exchange Act (17 CFR 240.14d–2(b))

☐ Pre–commencement communications pursuant to Rule 13e–4(c) under the Exchange Act (17 CFR 240.13e–4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value per share	OCGN	The Nasdaq Stock Market LLC (The Nasdaq Capital Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

Attached as Exhibit 99.1 hereto and incorporated herein by reference is a presentation that Ocugen, Inc. may use from time to time in presentations or discussions with investors, analysts, and other parties.

Item 9.01 Financial Statements and Exhibits.

The following exhibits are being filed herewith:

(d) Exhibits

Exhibit No.	Document
99.1	Ocugen, Inc. Presentation.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

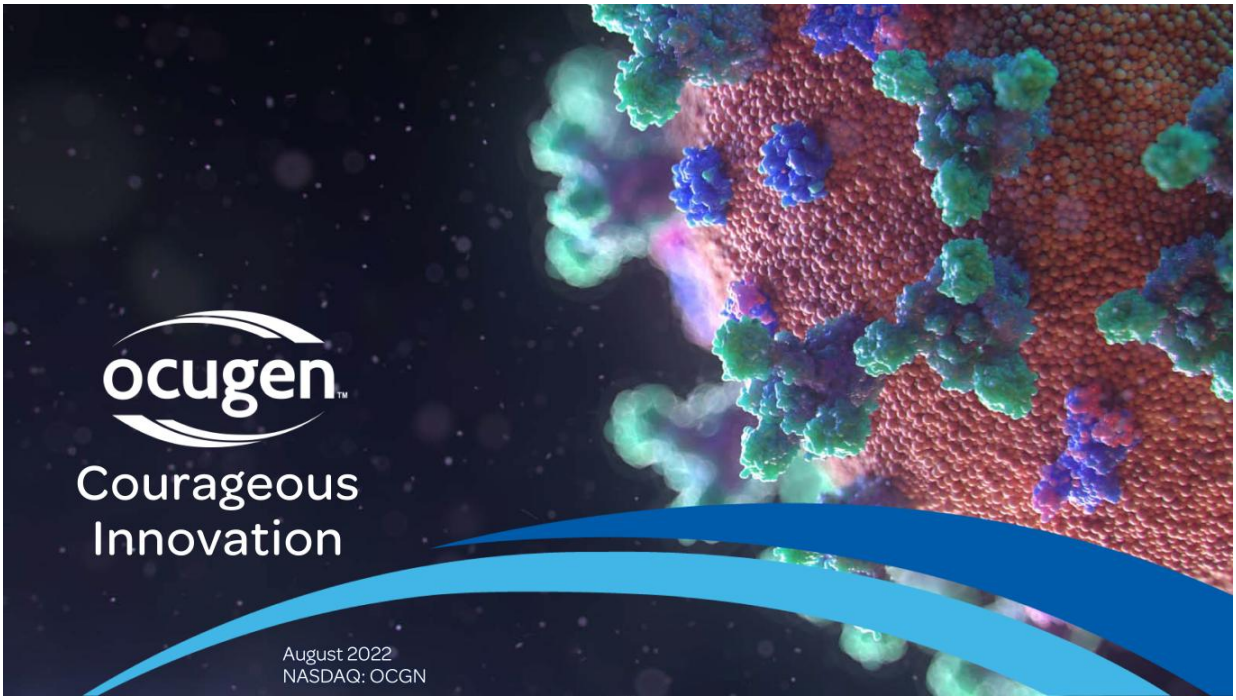
SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 16, 2022

OCUGEN, INC.

By: /s/ Shankar Musunuri
Name: Shankar Musunuri
Title: Chief Executive Officer and Chairman


ocugen™
Courageous
Innovation
August 2022
NASDAQ: OCGN

Forward Looking Statements

This presentation contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, which are based on the beliefs and assumptions of Ocugen, Inc. and on information currently available to management. All statements contained in this presentation other than statements of historical fact are forward-looking statements. We may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such statements are subject to numerous important factors, risks, and uncertainties that may cause actual events or results to differ materially from our current expectations. These and other risks and uncertainties are more fully described in our periodic filings with the Securities and Exchange Commission (SEC), including the risk factors described in the section entitled "Risk Factors" in the quarterly and annual reports that we file with the SEC. Forward-looking statements that we make in this presentation are based on a combination of facts and factors currently known to us and speak only as of the date of this presentation. Except as required by law, we assume no obligation to update forward-looking statements contained in this presentation whether as a result of new information, future events, or otherwise, after the date of this presentation.

We're Here to Make an Impact Through *Courageous Innovation*

Mission: At Ocugen, we are developing novel solutions to medical challenges, approaching healthcare innovation with purpose and agility to deliver new options for people facing serious disease and conditions

Pioneering a breakthrough modifier gene therapy for several vision impairment diseases

Innovating a novel biologic to treat eye diseases that can lead to vision loss for millions of people

Co-developing a COVID-19 vaccine

Creating a restorative cell therapy (RCT) platform to treat serious conditions like articular cartilage lesions

Pipeline Overview

	Asset/Program	Indication	Status
Vaccine	COVAXIN™ (BBV152) SARS-CoV-2 virus	COVID-19	• EUA for adults in Mexico; EUA for 2 to 18-year-olds pending* • U.S. Phase 2/3 Immuno-bridging and broadening clinical trial in-progress • Health Canada NDS under review*
Cell therapy	NeoCart® (Autologous chondrocyte-derived neocartilage)	Treatment of Articular Cartilage Defects in the Knee	U.S. Regenerative Medicine Advanced Therapy (RMAT) designation; Phase 3 clinical trial under development
Modifier Gene Therapy Platform	OCU400 *** AAV-hNR2E3	Gene mutation-associated retinal degeneration**	
		NR2E3 Mutation	Phase 1/2
		RHO Mutation	Phase 1/2
		CEP290 Mutation	To be submitted
	OCU410 AAV-hRORA	Dry Age-Related Macular Degeneration (Dry AMD)**	Preclinical
Novel Biologic	OCU200 Transferrin – Tumstatin	Diabetic Macular Edema	Preclinical
		Diabetic Retinopathy	Preclinical
		Wet Age-Related Macular Degeneration (Wet AMD)	Preclinical

* Based on Bharat Biotech-sponsored clinical trials in India

** No approved therapies exist
https://www.aao.org/eye-health/diseases/retinitis-pigmentosa-treatment | https://www.aao.org/eye-health/diseases/amd-treatment

*** ORPHAN DRUG DESIGNATION in the US; Broad ORPHAN MEDICINAL PRODUCT DESIGNATION by the EC for the treatment of retinitis pigmentosa (RP) and Leber congenital amaurosis (LCA)

MODIFIER GENE THERAPY PLATFORM

Breakthrough technology designed to address many rare diseases
as well as complex diseases that affect millions

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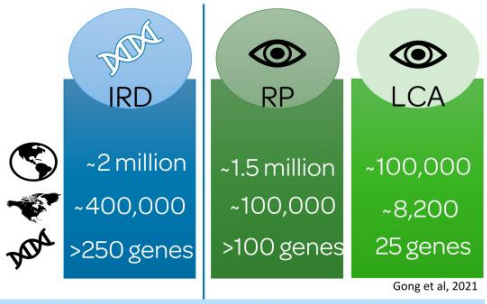
Prevalence of IRDs and Associated Genes

Heterogeneous disease with many gene mutations involved



Gong et al, 2021

- Only one approved gene therapy for LCA associated with *RPE65* mutation: Luxturna® (Voretigene Neparvovec)
- Electronic Smart Glasses are used to enable low vision aid in retinitis pigmentosa (RP) patients –IrisVision is a Class I medical device FDA approved for RP
- No treatment options are available for RP

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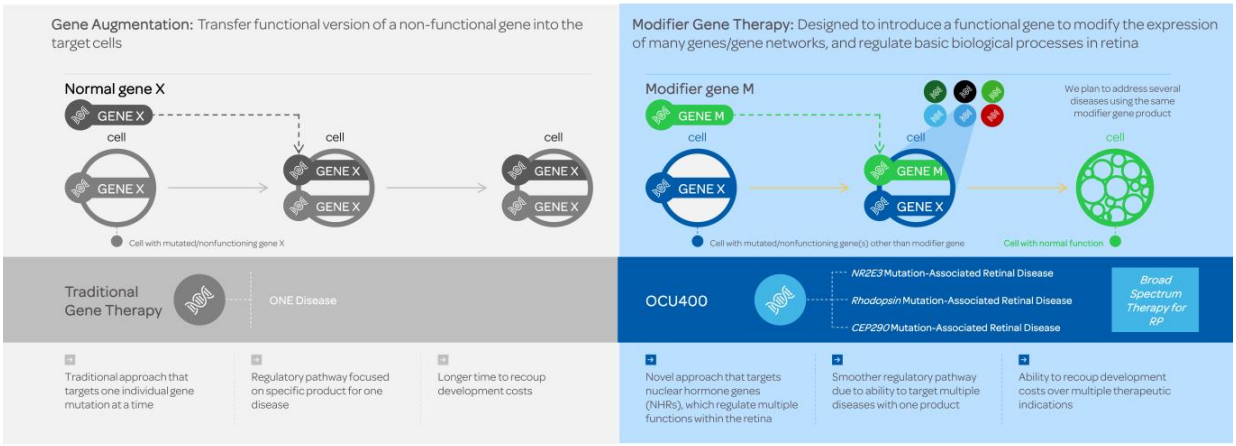
Our Vision: Inherited Retinal Diseases

Modifier Gene Therapy vs Traditional Gene Augmentation

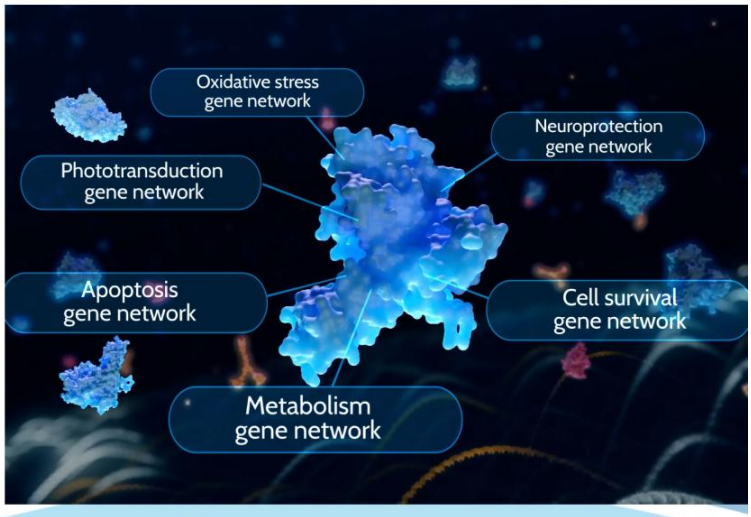


Our Focus: Nuclear Hormone Receptor Genes (NHRs)

NHRs in the retina are modulators of retinal development & function, acting as "master genes" in the retina

Molecular reset of key transcription factors and associated gene networks – retinal homeostasis

Gene modifier concept, including its impact on clinical phenotypes, is well known in other disease areas, such as cystic fibrosis and spinal muscular atrophy



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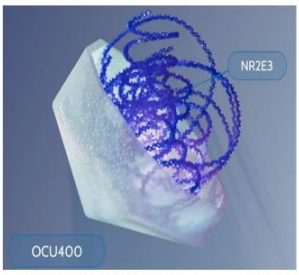
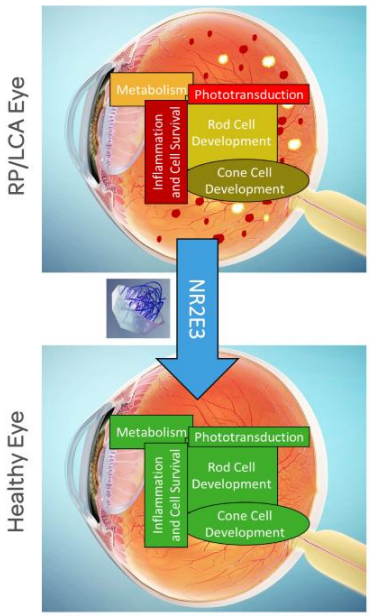
*References:
https://pubmed.ncbi.nlm.nih.gov/28556246/ | https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5409218/
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4339951/ |
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0183526

Ocugen's Modifier Gene Therapy Regulates Gene Networks



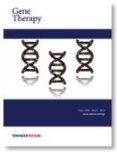
OCU400, NR2E3 gene within the AAV5 capsid

NR2E3 modifier gene therapy to restore retinal homeostasis



Proof of Principle: Published in Nature Gene Therapy

- Efficacy results shown in five unique mouse models of RP
- Technology developed at Harvard Medical School, Dr. Neena Haider's Lab
- Study suggests potency of modifier gene therapy to elicit broad-spectrum therapeutic benefits in early and advanced stages of RP
- Results suggest evidence of vision rescue in early & advanced stages of disease



Important milestone for development of therapy; demonstrated proof of principle

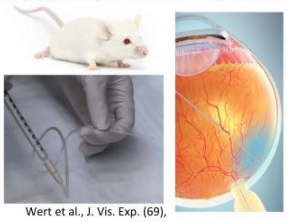
Protection elicited in multiple animal models of degeneration caused by different mutations

Potential to represent first broad-spectrum gene agnostic therapy and provide rescue even after disease onset

nature research
https://www.nature.com/articles/s41434-020-0134-z

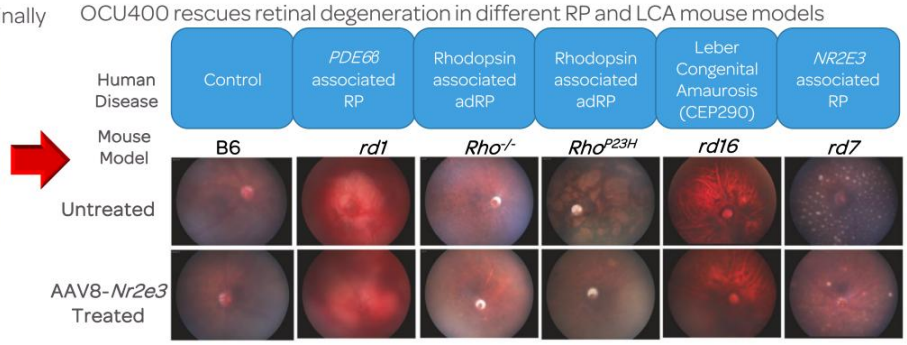
OCU400 Pharmacological Studies

OCU400 administered subretinally

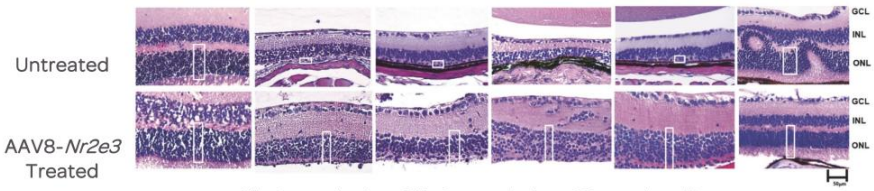


Wert et al., J. Vis. Exp. (69), 2012

OCU400 rescues retinal degeneration in different RP and LCA mouse models



OCU400 was tested in five different mouse models of retinal degeneration



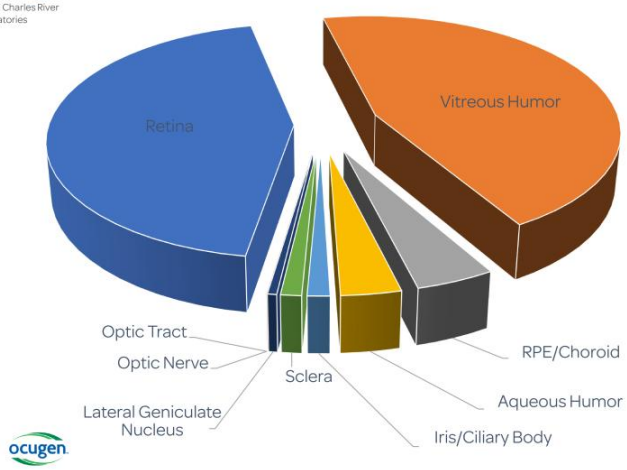
INL – Inner nuclear layer, ONL - Outer nuclear layer, GCL – ganglion cell layer

OCU400 Biodistribution, Safety and Toxicity Studies

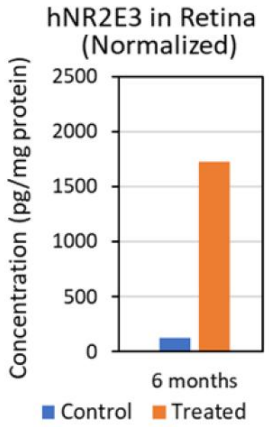
Image: Charles River Laboratories

OCU400 distribution in ocular tissues at six months post-dosing

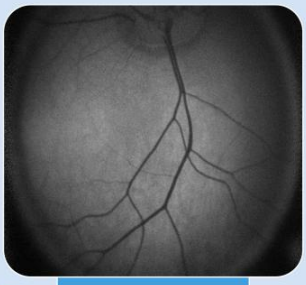
Relative tissue distribution



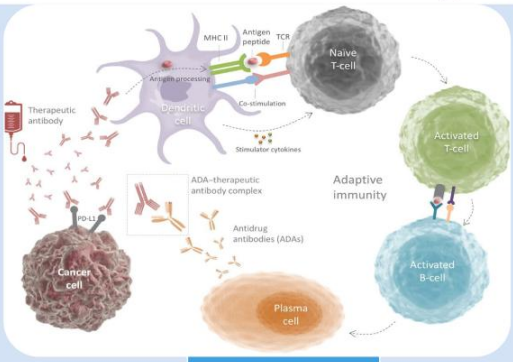
NR2E3 protein expression in the retina following OCU400 administration



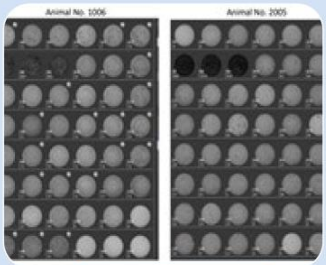
OCU400 Well Tolerated and Not Immunogenic



No toxic effects related to OCU400



No ADA response in serum or aqueous humor



No immunogenic response in PBMCs or lymphocytes

OCU400 Phase 1/2 Clinical Trial Progress

✓ Just 30 days to receive FDA clearance for Phase 1/2 gene therapy clinical trial

OCU400

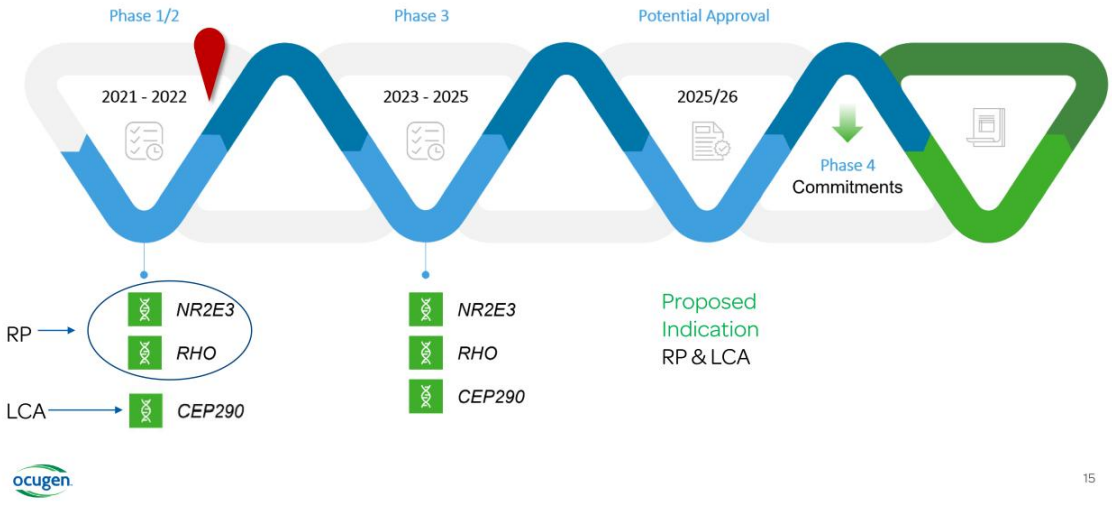
*A Phase 1/2 Study to Assess the Safety and Efficacy of **OCU400** for Retinitis Pigmentosa Associated with NR2E3 (Nuclear Receptor Subfamily 2 Group E Member 3) and RHO (Rhodopsin) Mutations*

NCT:	05203939
Study Type:	Interventional (Clinical Trial)
Estimated Enrollment:	18 participants
Clinical Trial Sites:	Seven
Allocation:	Non-randomized
Intervention Model:	Sequential assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Dosing:	Escalation study involving low, medium, high doses

Cohort 1	Cohort 2	Cohort 3
✓ Completed	In-progress	Pending
Low dose *First dose March 2022* *No serious adverse events reported*	*Medium dose* *First dose planned for August 2022* *Initiated dosing based on DSMB recommendation*	*High dose* *To be initiated*

Enrollment expected to conclude by YE 2022

OCU400 Pathway to Phase 3 Clinical Trials

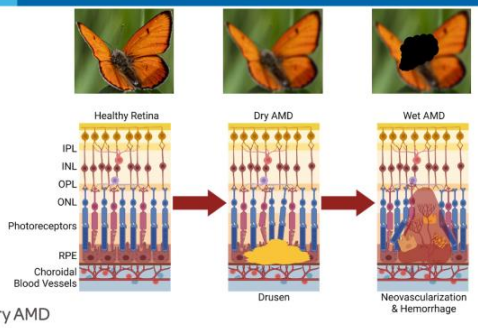


OCU410

Modifier Gene Therapy Platform

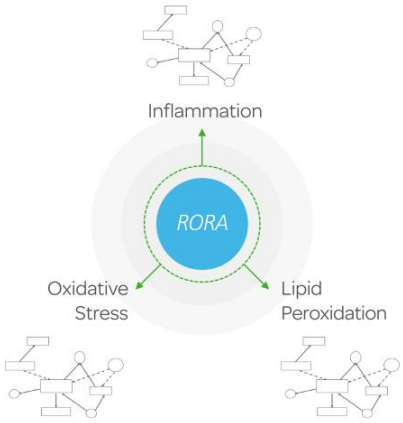
OCU410 (AAV-RORA) Dry Age-Related Macular Degeneration

We believe OCU410 has the potential to address this disease through its multi-factor approach



Dry AMD

- Leads to irreversible blindness due to degeneration of the retina
- ~9-10M patients in the U.S.
- Currently no approved treatment for Dry AMD
- Contributing factors: aging, genetics, environmental factors



We are executing pre-IND studies to support a planned 2023 Phase 1/2 clinical trial

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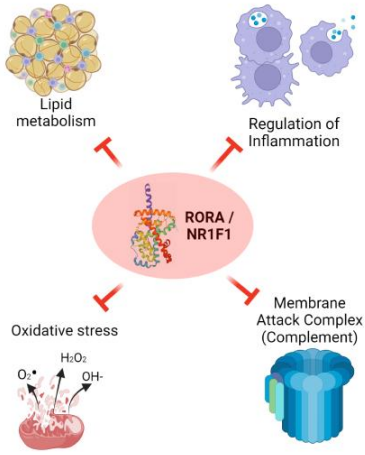
Sources
https://www.brightfocus.org/macular/article/age-related-macular-facts-figures
https://www.uniprot.org/uniprot/P35398#function
https://pubmed.ncbi.nlm.nih.gov/21998696/
https://pubmed.ncbi.nlm.nih.gov/19786043/

OCU410 (RORA) A Potential Modifier Therapeutic for Dry-AMD

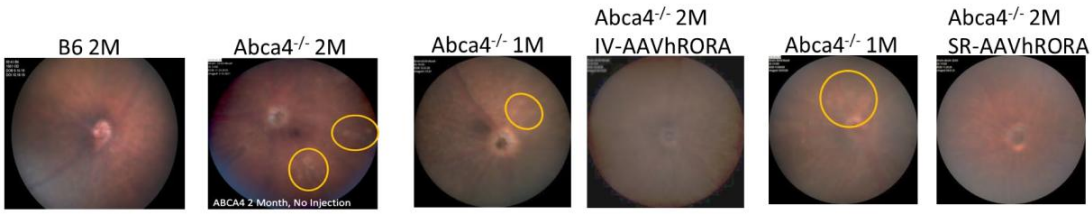
- **Genetic modifiers** are genes like Nuclear Hormone Receptors (NHR) that can:
  a) Significantly affect disease outcomes such as onset, rate of progression, and severity
  b) Enhance or suppress disease phenotypes
  c) Regulate cellular homeostasis

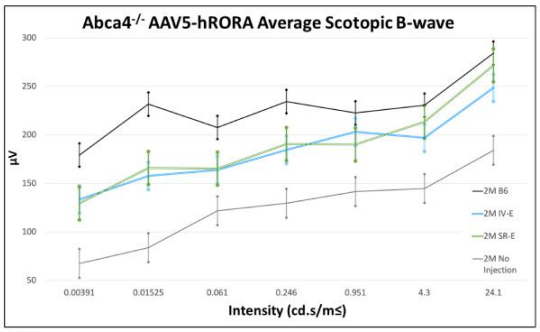
- The Retinoic Acid Related (RAR) Orphan Receptor Alpha (**RORA**) is a member of the NR1 subfamily of NHRs and regulates several gene networks

OCU410 is an adeno-associated virus-based vector containing Human RORA (isoform 1)



OCU410 Reduces Drusen in Abca4 -/- Mice, Improves Function





- ABCA4 is a retina-specific protein localized in outer segment disk edges of rod photoreceptors
- Mutations in ABCA have been linked to:
  a) Age-related macular degeneration (AMD)
  b) Stargardt macular dystrophy (STGD)
  c) Recessive RP
  d) Recessive cone-rod dystrophy
- OCU410 reduces drusen in Abca4 -/- mice and improves retinal function

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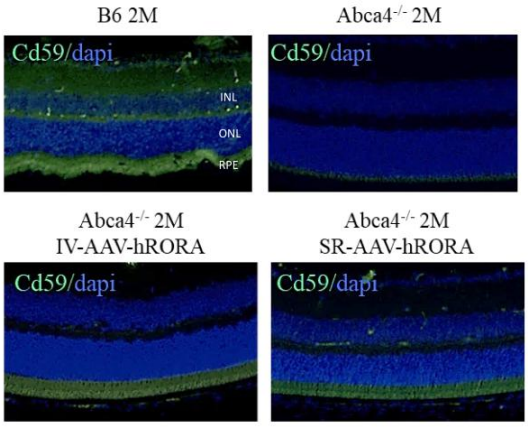
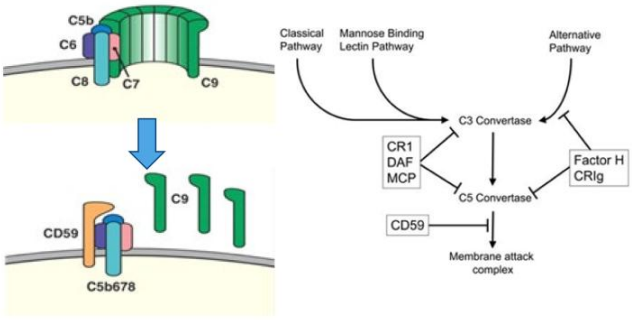
OCU410 Restores Cd59 Expression in Abca4-/- mice



IV - Intravitreal; SR-Subretinal; B6 - C57BL/6mice
INL - Inner nuclear layer, ONL - outer nuclear layer
RPE – Retinal Pigment Epithelium

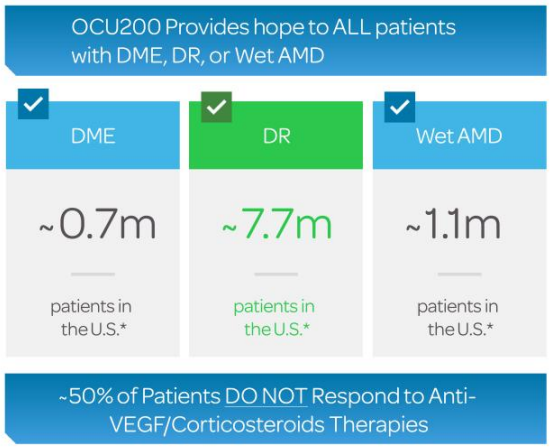


- Abca -/- mice show very low CD59 expression in their retinas
- CD59 prevents the formation of the complement membrane attack complex (MAC)
- OCU410 administered by intravitreal or subretinal routes restores CD59 expression in the RPE cells in the retina

OCU200

Novel biologic for treating Diabetic Macular Edema (DME), Diabetic Retinopathy (DR) and Wet Age-Related Macular Degeneration (Wet AMD)

OCU200 Potential to Treat DME, DR & Wet AMD



- OCU200 is a Transferrin-Tumstatin Fusion Protein
  - Tumstatin: Multiple Mechanisms of Action (MOAs) for treatment and prevention of macular edema and neovascularization
  - Transferrin: Targets the site of action and improves uptake (better target engagement)
- Integrin Targeting provides hope to these patients who are non-responders to current therapies
- Distinct MOA through targeting Integrin pathways can potentially also help reduce number of injections for patients who do respond to Anti-VEGF & corticosteroids therapies
- We are executing pre-IND studies to support a planned 2023 Phase 1 clinical trial

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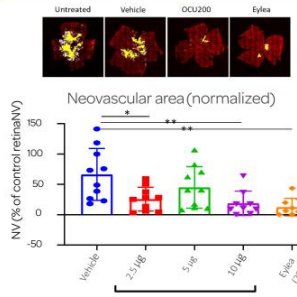
(*) https://www.gene.com/stories/retinal-diseases-fact-sheet
https://www.brightfocus.org/macular/article/age-related-macular-facts-figures

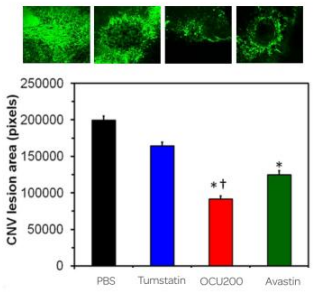
OCU200 Demonstrated Superior Efficacy Compared to Existing Anti-VEGF Therapies

DME/DR
Oxygen-Induced Retinopathy (OIR) Mouse Model



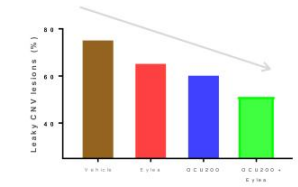
Effect of OCU200 intravitreal treatments on Neovascularization (NV). Data are presented as mean± SD. Filled circles represent data points from individual eyes
* P < 0.05, ** P < 0.01 (n = 9-10 eyes per group)

Wet AMD
In-Vivo Laser-Induced Rat CNV Model



* indicates p<0.05 when compared to PBS and/or tumstatin treatment
† indicates p<0.05 when compared to Avastin; CNV lesions measured on day 14 after treatment

Wet AMD
In-Vivo Laser-Induced Mouse CNV Model



Data expressed as percentage of CNV lesions on Day 10 after treatment. Laser induction & treatment start on Day 0

Ocugen™ Vision

Fully integrated, patient-centric biotech company focused on vaccines in support of public health and gene and cell therapies targeting unmet medical needs through **Courageous Innovation**


ocugen
Thank you!
August 2022
NASDAQ: OCGN